Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13365

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

Page ___ of ___

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence # 97488

13365

A. Patient information

1. Patient identifier [redacted] In confidence

2. Age at time of event: 49 or Date of birth: [redacted]

3. Sex: ☒ female ☐ male

4. Weight: 114 lbs or ___ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☒ other: Anemia, Thrombocytopenia

3. Date of event (mo/day/yr): 11/12/98

4. Date of this report (mo/day/yr): 2/5/99

5. Describe event or problem

Patient used this product for 3 mo prior to 11/12/98. She developed an anemia + Thrombocytopenia which resolved over 2 ½ mo after the product was stopped

6. Relevant tests/laboratory data, including dates

See enclosed sheet

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Asthma, Hay fever

Has used bethune tablets + albuterol inhaler prn for years

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Spark Nutritional Beverage
- #2

2. Dose, frequency & route used
- #1
- #2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 8/15/98 – 11/12/98
- #2

4. Diagnosis for use (indication)
- #1
- #2

5. Event abated after use stopped or dose reduced
- #1 ☒ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☒ doesn't apply
- #2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # (for product problems only) – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
- model #
- catalog #
- serial #
- lot #
- other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address [redacted] phone # [redacted]

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2. Health professional? ☒ yes ☐ no

3. Occupation: Internal Medicine

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 97488

PLEASE TYPE OR USE BLACK INK

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
**The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787**

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Notes on Telephone Conversation
Clinical Research and Review Staff

Date	5 March 99	Phone No.	[redacted]
Name	[redacted] MD	Fax No.	
Affliation			
Address	[redacted]		
FDA Representatives	Dr. Richard Calvert		
Question/Subject	F/u on ARMS 97488 - How many and which products was his patient using when the adverse event reported 2-5-99 occurred?		

Discussion	Dr. [redacted] spoke with me after I had identified myself as an FDA medical officer following up on his MedWatch report. He was unsure if his patient had used the other products (included were labels of these) along with "Spark Nutritional Beverage" he noted on the MedWatch form. He suggested I contact his patient directly, and gave me her telephone number.

Follow up	Will contact consumer with above question.

Signed: Richard J. Calvert, MD Date: 5 Mar 99

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Notes on Telephone Conversati
Clinical Research and Review Staff

Date	5 Mar 99	Phone No.	[redacted]
Name	[redacted]	Fax No.	
Affliation	(consumer)		
Address			
FDA Representatives	Dr. Richard J. Calvert		
Question/Subject	F/U on ARMS # 97488 - Which supplement(s) were used prior to adverse event reported to Dr. [redacted]?		

Discussion	After obtaining permission from Dr. [redacted], I telephoned Mrs [redacted] at her workplace & identified myself as an FDA Medical Officer. I asked her which supplements she was using prior to her adverse event. She told me she used 3 - the Spark Nutritional Beverage (once per day), The Silver Packet (2 grey caplets, 1 brown caplet, 1 tan caplet) twice per day, and The White Packet (3 yellow caplets) once per day. She had used the 2 packets for about 6 months prior to the adverse event, and the Spark beverage for about 3 months prior to the adverse event. This usage was as described on the labels, except that she used the Spark beverage only once per day.

Follow up	

Signed: Richard J Calvert Date: 5 Mar 99